point as a waypoint (WP), in error. This action makes editorial corrections to the reference of the TONOC, WI, WP to change it to be reflected as a Fix. This correction is necessary to match the FAA National Airspace System Resource (NASR) database information.

DATES: Effective date 0901 UTC, December 29, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule in the **Federal Register** (87 FR 65521; October 31, 2022), amending VOR Federal airways V–26 and V–63; establishing RNAV route T–464; and revoking the Wausau, WI, Low Altitude Reporting Point in the vicinity of Wausau, WI. Subsequent to publication, the FAA determined that the TONOC, WI, route point was inadvertently identified as a WP, in error. The correct route point reference is the TONOC, WI, Fix. This rule corrects that error by changing the reference of the TONOC, WI, WP to the TONOC, WI, Fix.

This is an editorial change only to match the FAA NASR database information and does not alter the alignment of the affected T–464 route.

United States Area Navigation Routes are published in paragraph 6011 of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The RNAV T-route listed in this document will be published subsequently in FAA Order JO 7400.11.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, references to the TONOC, WI, WP that is reflected in Docket No. FAA–2022–0243, as published in the **Federal Register** of October 31, 2022 (87 FR 65521), FR Doc. 2022–22165, is corrected as follows:

■ 1. On page 65523, correct the table for T–464 CUSAY, WI to CHURP, WI [New] to read:

T–464 CUSAY, WI TO CHURP, WI [NEW]		
CUSAY, WI	WP	(Lat. 46°01′07.84″ N, long. 091°26′47.14″ W)
TONOC, WI	FIX	(Lat. 45°03′47.56 ″ N, long. 091°38′11.87″ W)
EDGRR, WI	WP	(Lat. 44°51′31.83″ N, long. 089°56′43.06″ W)
HEVAV, WI	WP	(Lat. 44°50′48.43″ N, long. 089°35′12.51″ W)
CHURP, WI	FIX	(Lat. 44°42′54.82″ N, long. 088°56′48.69″ W)

* * * * *

Issued in Washington, DC, on November 3, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–24387 Filed 11–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–990]

Schedules of Controlled Substances: Placement of Ganaxolone in Schedule V

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule adopts, without change, an interim final rule with request for comments published in the **Federal Register** on June 1, 2022, placing ganaxolone (3α-hydroxy-3β-methyl-5α-pregnan-20-one) and its salts in schedule V of the Controlled Substances Act. With the issuance of this final rule, the Drug Enforcement Administration maintains ganaxolone, including its salts, in schedule V of the Controlled Substances Act.

DATES: The effective date of this rule is December 9, 2022.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Ph.D., Chief, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

Under the Controlled Substances Act (CSA), as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (Pub. L. 114–89), when the Drug Enforcement Administration (DEA) receives notification from the Department of Health and Human Services (HHS) that the Secretary has approved a certain new drug and HHS recommends control in the CSA schedule II–V, DEA is required to issue an interim final rule (IFR), with opportunity for public comment and to request a hearing, controlling the drug within a specified 90-day timeframe and subsequently to issue a final rule. 21 U.S.C. 811(j). When controlling a drug pursuant to subsection (j), DEA must apply the scheduling criteria of 21 U.S.C. 811 (b) through (d) and 812(b). 21 U.S.C. 811(j)(3).

On March 18, 2022, DEA received notification that FDA approved, on that same date, a new drug application for ZTALMY (ganaxolone oral suspension) for the treatment of seizures associated with cyclin-dependent kinase-like 5 deficiency disorder in patients two years or older. In addition, on March 14, 2022, HHS recommended that DEA place ganaxolone and its salts in schedule V of the CSA. On June 1, 2022, DEA, pursuant to 21 U.S.C. 811(j), published an IFR in the **Federal Register** to make ganaxolone (including its salts) a schedule V controlled substance. 87 FR 32991.

The IFR referenced two supporting documents and stated they were available for viewing on the electronic docket. Specifically, the two documents cited are as follows: (1) HHS's March 2022 scientific and medical evaluation and scheduling recommendation (HHS Eight-Factor analysis), and (2) DEA's May 2022 Eight-Factor analysis. DEA has discovered that these documents were not posted to the electronic docket. However, they were available for viewing at DEA headquarters. Upon publication of this final rule, DEA will post to the docket DEA's and HHS's analyses that should have accompanied the IFR.

The IFR provided an opportunity for interested persons to submit comments, as well as file a request for a hearing or waiver of a hearing, on or before July 1, 2022. DEA did not receive any comments or requests for a hearing or

waiver of a hearing. Based on the rationale set forth in the IFR, DEA adopts the IFR, without change.

Requirements for Handling Ganaxolone

As indicated above, ganaxolone has been a schedule V controlled substance by virtue of an IFR issued by DEA in June 2022. Thus, this final rule does not alter the regulatory requirements applicable to handlers of ganaxolone that have been in place since that time. Nonetheless, for informational purposes, we restate here those requirements. Ganaxolone is subject to the CSA's schedule V regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importing, exporting, research, and conduct of instructional activities and chemical analysis with, and possession involving schedule V substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, ganaxolone must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312. Any person who intends to handle ganaxolone and is not registered with DEA must submit an application for registration and may not handle ganaxolone unless DEA has approved that application, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. These registration requirements, however, are not applicable to patients (end users) who possess ganaxolone pursuant to a lawful prescription.

2. *Disposal of stocks.* Any person who obtains a schedule V registration to handle ganaxolone and subsequently determines they are no longer willing or able to maintain such registration must surrender all quantities of ganaxolone, or may transfer all quantities of ganaxolone to a person registered with DEA. Ganaxolone must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Ganaxolone is subject to schedule III–V security requirements for DEA registrants, and it must be handled and stored in accordance with 21 CFR 1301.71–1301.77. Non-practitioners handling ganaxolone must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93. These requirements, however, are not applicable to patients (end users) who possess ganaxolone pursuant to a lawful prescription.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of ganaxolone must comply with 21 U.S.C. 825, and be in accordance with 21 CFR part 1302.

5. *Inventory.* Since June 1, 2022, every DEA registrant who possesses any quantity of ganaxolone was required to keep an inventory of ganaxolone on hand, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. These requirements, however, are not applicable to patients (end users) who possess ganaxolone pursuant to a lawful prescription.

6. *Records and Reports.* DEA registrants must maintain records and submit reports for ganaxolone, pursuant to 21 U.S.C. 827 and 832(a), and in accordance with 21 CFR 1301.74(b) and (c) and 1301.76(b) and parts 1304, 1312, and 1317.

7. *Prescriptions.* All prescriptions for ganaxolone, or products containing ganaxolone, must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

8. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule V controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of ganaxolone may only be for the legitimate purposes consistent with the drug's labeling, or for research activities authorized by the Federal Food, Drug, and Cosmetic Act, as applicable, and the CSA.

9. *Importation and Exportation.* All importation and exportation of ganaxolone must comply with 21 U.S.C. 952, 953, 957, and 958, and be in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving ganaxolone not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Administrative Procedure Act

This final rule, without change, affirms the amendment made by the IFR that is already in effect. Section 553 of the Administrative Procedure Act (5 U.S.C. 553) generally requires notice and comment for rulemakings. However, 21 U.S.C. 811(j) provides that in cases where a certain new drug is (1) approved by HHS, under section 505(c) of the Federal Food, Drug, and Cosmetic Act, and (2) HHS recommends control in CSA schedule II–V, DEA shall issue an IFR scheduling the drug within 90 days. Additionally, subsection (j) specifies that the rulemaking shall become immediately effective as an IFR without requiring DEA to demonstrate good cause. DEA issued an IFR on June 1, 2022, and solicited public comments on that rule. Subsection (j) further provides that after giving interested persons the opportunity to comment and to request a hearing, the Attorney General, as delegated to the Administrator of DEA, shall issue a final rule in accordance with the scheduling criteria of 21 U.S.C. 811(b) through (d) and 812(b). As stated above, DEA did not receive any comments or requests for a hearing or waiver of a hearing. DEA is now issuing the final rule in accordance with subsection (j).

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a) and (j), this scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA. As noted in the above discussion regarding the applicability of the APA, DEA was not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply to this final rule.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

Accordingly, the interim final rule amending 21 CFR part 1308, which published on June 1, 2022 (87 FR 32991), is adopted as a final rule without change.

Signing Authority

This document of the Drug Enforcement Administration was signed on November 1, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2022–24157 Filed 11–8–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–1046]

Specific Listing for 1-boc-4-AP, a Currently Controlled List I Chemical

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is establishing a specific listing and DEA Chemical Control Number for *tert*-butyl 4-(phenylamino)piperidine-1-carboxylate (also known as 1-boc-4-AP; and CAS Number: 125541–22–2) and its salts as a list I chemical under the Controlled Substances Act. Although 1-boc-4-AP is not specifically listed as a list I chemical of the Controlled Substances Act with its own unique Chemical Control Number, it has been regulated as a list I chemical in the United States since May 15, 2020, as a carbamate of *N*-phenylpiperidin-4-amine, a list I chemical. Therefore, DEA is simply amending the list I chemicals list in its regulations to include a separate listing for 1-boc-4-AP, a currently controlled list I chemical.

DATES: Effective date November 9, 2022.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION: *tert*-Butyl 4-(phenylamino)piperidine-1-carboxylate (also known as 1-boc-4-AP) is a chemical that is structurally related to *N*-phenylpiperidin-4-amine (also known as *N*-phenyl-4-piperidinamine, 4-anilinopiperidine, and 4-AP). *N*-Phenylpiperidin-4-amine, including its amides, its carbamates, and its salts, is listed as a list I chemical at 21 CFR 1310.02(a). See 85 FR 20822 (April 1, 2020) (effective May 15, 2020). The chemical structure of 1-boc-4-AP defines it as a carbamate of *N*-phenylpiperidin-4-amine. Accordingly, under 21 CFR 1310.02(b), 1-boc-4-AP, as a carbamate of *N*-phenylpiperidin-4-amine, is and continues to be a regulated list I chemical.[1]

Legal Authority

The Controlled Substances Act (CSA) and the Drug Enforcement Administration's (DEA) implementing regulations give the Attorney General, as delegated to the Administrator of DEA (Administrator), the authority to specify, by regulation, a chemical as a ''list I chemical.'' [2] This term refers to a chemical that is used in manufacturing a controlled substance in violation of subchapter I (Control and Enforcement) of the CSA and is important to the manufacture of the controlled substance.[3] The current list of all list I chemicals is available in 21 CFR 1310.02(a).

In addition, the United States is a Party to the 1988 United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988 Convention), December 20, 1988, 1582 U.N.T.S. 95. Under Article 12 of the 1988 Convention, when the United States receives notification that a chemical has been added to Table I or Table II of the 1988 Convention, the United States is required to take measures it deems appropriate to monitor the manufacture and distribution of that chemical within the United States and to prevent its diversion, including measures related to international trade.

Background

In a letter dated May 27, 2022, the United Nations Office on Drugs and Crime, in accordance with Article 12, paragraph 6 of the 1988 Convention, informed the Permanent Mission of the United States of America to the United Nations (Vienna) that the Commission on Narcotic Drugs (CND) decided to place the chemical 1-boc-4-AP in Table I of the 1988 Convention (CND Dec/65/5) at its 65th Session on March 16, 2022.

[1] *N*-phenylpiperidin-4-amine, including its amides, its carbamates, and its salts, has been subject to list I chemical regulations since May 15, 2020, pursuant to a final rule (April 15, 2020; 85 FR 20822).

[2] 21 U.S.C. 802(34) and 871(b) and 21 CFR 1310.02(c).

[3] 21 U.S.C. 802(34) and 21 CFR 1300.02(b).